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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/803,687	03/09/2001	David T. Scadden	0492479-0018	7008

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EXAMINER

KATCHEVES, KONSTANTINA T

ART UNIT

PAPER NUMBER

1636

DATE MAILED: 09/08/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

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**Advisory Action**

**Application No.**

09/803,687

**Applicant(s)**

SCADDEN ET AL.

**Examiner**

Konstantina Katcheves

**Art Unit**

1636

**--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

THE REPLY FILED 16 August 2004 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

**PERIOD FOR REPLY** [check either a) or b)]

- a) ☒ The period for reply expires 3 months from the mailing date of the final rejection.
- b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection. ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☐ A Notice of Appeal was filed on \_\_\_\_\_. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.
2. ☐ The proposed amendment(s) will not be entered because:
- (a) ☐ they raise new issues that would require further consideration and/or search (see NOTE below);
  - (b) ☐ they raise the issue of new matter (see Note below);
  - (c) ☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
  - (d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: \_\_\_\_\_.

3. ☐ Applicant's reply has overcome the following rejection(s): \_\_\_\_\_.
4. ☐ Newly proposed or amended claim(s) \_\_\_\_\_ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
5. ☒ The a) ☐ affidavit, b) ☐ exhibit, or c) ☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because: See below.
6. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.
7. ☒ For purposes of Appeal, the proposed amendment(s) a) ☐ will not be entered or b) ☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:

Claim(s) allowed: \_\_\_\_\_.

Claim(s) objected to: \_\_\_\_\_.

Claim(s) rejected: 1-32, 34-37, 42-45, 75.

Claim(s) withdrawn from consideration: \_\_\_\_\_.


8. ☐ The drawing correction filed on \_\_\_\_\_ is a) ☐ approved or b) ☐ disapproved by the Examiner.
9. ☐ Note the attached Information Disclosure Statement(s) (PTO-1449) Paper No(s). \_\_\_\_\_.
10. ☐ Other: \_\_\_\_\_.

Continuation of 5. NOTE: Applicant's response fails to overcome the pending rejections under 35 U.S.C. 102, 35 U.S.C. 103 and the pending rejection under 35 U.S.C 112, first paragraph. With regard to the rejections under 35 U.S.C. 102 that the prior art fails to provide an enabling disclosure. It is noted that the test for "enabling disclosure" is whether the public was in possession of the claimed invention before the date of invention. See MPEP 2121.01 "Such possession is effected if one of ordinary skill in the art could have combined the publication's description of the invention with his [or her] own knowledge to make the claimed invention." See MPEP 2101.01 citing *In re Donohue*, 766 F.2d 531, 226 USPQ 619 (Fed. cir. 1985).

*Roberts et al.* discloses that the p21 along with p27 could be inhibited to increase the proportion of proliferating cells in a population. The fact that *Roberts et al.* disclosed other protein targets thought to be involved in cell cycle control and did not try every combination does not render the invention inoperable. Indeed, *Roberts et al.* show that inhibition of p27 increases the proportion of proliferating cells in a population there is no reason to conclude that inhibiting another target protein involved in cell cycle control would render the disclosure inoperable. Moreover, *Roberts et al.* disclose antagonists of p21 such that one of skill in the art would not have to engage in undue experimentation to either make or use the method claimed.

Applicant asserts that independent claims 1, 3, and 30 only recite a decrease in p21 activity and do not recite a decrease in both p21 and p27 activity. Applicant should note that the claim recites open language and is therefore not limited to an increase in only p21 activity. Applicant's arguments regarding the propriety of the rejection under 35 USC 103 rely on those arguments set forth with regard to *Roberts et al.* which have been addressed above. Applicant also argues that even if *Roberts et al.* is applicable as art, it fails to disclose the use of stem or progenitor cells in the method. This argument has been previously presented and rebutted with regard to the 102 rejection over *Roberts et al.* As stated in the final rejection, the cell populations include stem cells, progenitor cells, fibroblasts, myeloblasts, neurons, epithelial cells, hematopoietic progenitor cells, granulopoietic and embryogenic cells. See column 2, lines 64 to column 3 lines 11, column 20, and example 5.

Applicant argues that a manuscript by the inventors discloses that the transient reduction of p21 levels in cells treated with specific RNAi constructs targeting p21 obviates the rejection under 35 USC 112, first paragraph. Applicant should note that the arguments of counsel cannot take the place of evidence in the record. *In re Schulze*, 346 F.2d 600, 602, 145 USPQ 716, 718 (CCPA 1965); *In re Geisler*, 116 F.3d 1465, 43 USPQ2d 1362 (Fed. Cir. 1997). Indeed such data may be useful in overcoming such a rejection. However, it would require full consideration of the examiner.



JAMES KETTER  
PRIMARY EXAMINER